



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

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Peer SCHENK and Philippe HERVÉ,
NexGen Plants Pty. Ltd.
Staff Level 7, House GPS Road Bldg
The University of Queensland
P.O. Box 6069
St. Lucia QLD 4067 Australia

Re: Confirmation of the regulatory status of virus resistant tomato (*Solanum lycopersicum*) lines NP-TV101-1, NP-TV101-2, NP-TV101-3, NP-TV201-1, NP-TV201-2, and NP-TV201-3.

Dear Peer SCHENK and Philippe HERVÉ,

Thank you for your letter dated February 6th, 2019, inquiring whether the tomato (*Solanum lycopersicum*) products described in your letter are regulated articles under 7 CFR part 340. Your letter describes an intragenic method of inserting tomato DNA sequences into tomato, resulting in the desired virus-resistant phenotypes.

The Plant Protection Act (PPA) of 2000 gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds to protect the agriculture, environment, and economy of the United States.

USDA regulates the importation, interstate movement and environmental release (field testing) of certain genetically engineered (GE) organisms that are, or have the potential to be, plant pests. Regulations for GE organisms that are, or have the potential to be, plant pests under the PPA, are codified at 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." Under the provisions of these regulations, a GE organism is deemed a regulated article if it has been genetically engineered using a donor organism, recipient organism, or vector or vector agent that is listed in §340.2 and meets the definition of a plant pest, or that is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the GE organism is a plant pest or has reason to believe it is a plant pest.

According to your February 6th, 2019 letter, DNA constructs were directly introduced into tomato through the use of particle bombardment of gel-purified linearized DNA. Additionally, the entirety of the introduced DNA originated from the tomato genome; no sequences derived from plant pests were introduced into the plant. This intragenic method resulted in the production of tomato lines resistant to Tomato Spotted Wilt Virus (NP-TV201-1, NP-TV201-2, and NP-TV201-3) or Cauliflower Mosaic Virus (NP-TV101-1, NP-TV101-2, and NP-TV101-3). Virus resistance in these tomato lines is facilitated through the use of RNA interference (RNAi), a common mechanism used to directly silence plant viruses in order to develop resistance in plants.

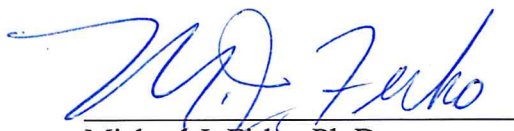
Based on the information you provided in your February 6th, 2019 letter, USDA has concluded that the virus-resistant GE tomato lines NP-TV101-1, NP-TV101-2, NP-TV101-3, NP-TV201-1, NP-TV201-2, and NP-TV201-3 are not plant pests. These virus-resistant tomato lines contain DNA sequences derived from tomato and introduction of these DNA sequences was performed utilizing particle bombardment. Therefore, consistent with previous responses to similar letters of inquiry, USDA does not consider virus-resistant GE tomato lines NP-TV101-1, NP-TV101-2, NP-TV101-3, NP-TV201-1, NP-TV201-2, and NP-TV201-3, as described in your February 6th, 2019 letter, to be regulated pursuant to 7 CFR part 340. Additionally, tomato is not listed as a Federal noxious weed pursuant to 7 CFR part 360, and USDA has no reason to believe that the virus-resistant phenotype in your GE tomato lines NP-TV101-1, NP-TV101-2, NP-TV101-3, NP-TV201-1, NP-TV201-2, and NP-TV201-3 would increase the weediness of tomato.

Please be advised that the importation of your GE tomato seeds or plants, like all other tomato, will be subject to Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these GE tomato seeds or plants, you may contact the PPQ general number for such inquiries at (877) 770-5990.

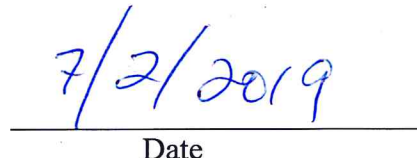
Please be advised that your virus-resistant GE tomato lines NP-TV101-1, NP-TV101-2, NP-TV101-3, NP-TV201-1, NP-TV201-2, and NP-TV201-3, while not regulated by APHIS under 7 CFR part 340 may still be subject to other regulatory authorities such as FDA or EPA.

Should you become aware at any time of any issues that may affect the Agency's conclusion regarding this inquiry, you must immediately notify the Agency in writing of the nature of the issue. We hope that you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,



Michael J. Firko, Ph.D.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture



Date